NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

TYCO HEALTHCARE GROUP LP and MALLINCKRODT INC., Plaintiffs, v. MUTUAL PHARMACEUTICAL COMPANY, INC. and UNITED RESEARCH LABORATORIES, INC., Defendants.	Civil Action No. 07-1299 (SRC) **OPINION & ORDER**

CHESLER, U.S.D.J.

This matter comes before the Court on the motion for partial summary judgment by Plaintiffs Tyco Healthcare Group LP and Mallinckrodt Inc. (collectively, "Tyco"). The Defendants are Mutual Pharmaceutical Company, Inc. and United Research Laboratories, Inc. (collectively, "Mutual"). For the reasons stated below, the motion for partial summary judgment will be granted in part and denied in part.

APPLICABLE LEGAL STANDARDS

I. Motion for summary judgment

Summary judgment is appropriate under FED. R. CIV. P. 56(c) when the moving party demonstrates that there is no genuine issue of material fact and the evidence establishes the moving party's entitlement to judgment as a matter of law. Celotex Corp. v. Catrett, 477 U.S. 317, 322-23 (1986). A factual dispute is genuine if a reasonable jury could return a verdict for the non-movant, and it is material if, under the substantive law, it would affect the outcome of

the suit. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986). "In considering a motion for summary judgment, a district court may not make credibility determinations or engage in any weighing of the evidence; instead, the non-moving party's evidence 'is to be believed and all justifiable inferences are to be drawn in his favor.'" Marino v. Indus. Crating Co., 358 F.3d 241, 247 (3d Cir. 2004) (quoting Anderson, 477 U.S. at 255).

"When the moving party has the burden of proof at trial, that party must show affirmatively the absence of a genuine issue of material fact: it must show that, on all the essential elements of its case on which it bears the burden of proof at trial, no reasonable jury could find for the non-moving party." In re Bressman, 327 F.3d 229, 238 (3d Cir. 2003) (quoting United States v. Four Parcels of Real Property, 941 F.2d 1428, 1438 (11th Cir. 1991)). "[W]ith respect to an issue on which the nonmoving party bears the burden of proof . . . the burden on the moving party may be discharged by 'showing' – that is, pointing out to the district court – that there is an absence of evidence to support the nonmoving party's case." Celotex, 477 U.S. at 325.

Once the moving party has satisfied its initial burden, the party opposing the motion must establish that a genuine issue as to a material fact exists. Jersey Cent. Power & Light Co. v. Lacey Township, 772 F.2d 1103, 1109 (3d Cir. 1985). The party opposing the motion for summary judgment cannot rest on mere allegations and instead must present actual evidence that creates a genuine issue as to a material fact for trial. Anderson, 477 U.S. at 248; Siegel Transfer, Inc. v. Carrier Express, Inc., 54 F.3d 1125, 1130-31 (3d Cir. 1995). "[U]nsupported allegations . . . and pleadings are insufficient to repel summary judgment." Schoch v. First Fid. Bancorporation, 912 F.2d 654, 657 (3d Cir. 1990); see also FED. R. CIV. P. 56(e) (requiring

nonmoving party to "set out specific facts showing a genuine issue for trial"). "A nonmoving party has created a genuine issue of material fact if it has provided sufficient evidence to allow a jury to find in its favor at trial." Gleason v. Norwest Mortg., Inc., 243 F.3d 130, 138 (3d Cir. 2001).

If the nonmoving party has failed "to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial, . . . there can be 'no genuine issue of material fact,' since a complete failure of proof concerning an essential element of the nonmoving party's case necessarily renders all other facts immaterial." Katz v. Aetna Cas. & Sur. Co., 972 F.2d 53, 55 (3d Cir. 1992) (quoting Celotex, 477 U.S. at 322-23).

ANALYSIS

I. Plaintiffs' motion for partial summary judgment

Mutual had appealed this Court's Order filed January 18, 2013, which granted in part and denied in part Tyco's motion for partial summary judgment. In its decision of August 6, 2014. the Federal Circuit affirmed in part, vacated in part, and remanded this case for further proceedings. Tyco Healthcare Group LP v. Mut. Pharm. Co., 762 F.3d 1338 (Fed. Cir. 2014). Presently before the Court is a motion for partial summary judgment on two issues raised in this Court's now-vacated decisions.

The Federal Circuit vacated two of this Court's decisions on the prior motion for partial summary judgment and remanded the case for further proceedings on these issues. The Federal Circuit vacated: 1) the grant of summary judgment that Tyco's infringement claims were not sham litigation; and 2) the grant of summary judgment that Tyco's citizen's petition to the FDA

was not a sham.

As to the issue of sham litigation, in the summary judgment decision filed January 18, 2013, this Court had granted Plaintiffs' motion for summary judgment that this infringement action did not fall within the sham litigation exception to Noerr-Pennington immunity. The Federal Circuit vacated this decision, remanding the case for further inquiry into Tyco's theory of infringement. 762 F.3d at 1345. The Federal Circuit stated:

> Tyco's infringement claim is based on its theory that Mutual's use of 40°C as the outgassing temperature was inappropriate and that 105°C—the temperature at which Tyco and Sandoz tested Restoril—should have been used instead. The parties do not dispute that the specific surface area of Mutual's temazepam falls within the infringing range when the outgassing temperature is set at 105°C. However, expert testimony and other evidence, including images from a scanning electron microscope, suggest that exposing Mutual's temazepam to a temperature of 105°C physically alters the temazepam material itself, resulting in larger temazepam particles and decreased specific surface area.
>
> In addition, testimony from Mutual's expert tends to establish that lower outgassing temperatures result in measurements that underestimate specific surface area. If that is true, the difference between the actual specific surface area of the tested product and the infringing range would actually be greater than indicated by the measurement of the tested product obtained at a lower outgassing temperature. According to Mutual's expert, increasing the outgassing temperature merely serves to accelerate the removal of contaminants from the surface of the tested material. If full outgassing is not achieved, the measured specific surface area may be reduced, because less surface area is available for the test gas to adsorb to. It therefore stands to reason that, barring physical alteration to Mutual's temazepam, Tyco's demand that Mutual increase the outgassing temperature would not decrease—but would potentially increase—the specific surface area measurement due to the removal of more surface contaminants. Barring physical alteration of the material, an increased outgassing temperature would thus make it more likely that Mutual's commercial product would measure outside of the infringing range, not more likely that it would measure within the infringing range, as Tyco suggests. Tyco's theory of why Mutual's as-marketed ANDA product will infringe therefore appears to be based on a theory contrary to what the underlying scientific principles dictate. Put simply, even if Mutual's specific surface area measurements are wrong, they would appear to be wrong in a way that does not help Tyco.

> Based on the evidence of record and this analysis, we conclude that further inquiry is needed into the effect of the outgassing temperature on the specific surface area of Mutual's generic product. We leave it to the district court to determine whether that inquiry can be performed within the context of a summary judgment proceeding or requires a trial. Accordingly, on remand, the district court should determine whether Tyco's factual theory of infringement is objectively baseless.

Id. Plaintiffs now move for summary judgment on this issue.

As the Federal Circuit stated, it did not have a full evidentiary record before it. It appears that the Court of Appeals was aware of only the opinions of Mutual's experts about the science underlying Tyco's theory of infringement, and those opinions, naturally, suggested that Tyco's infringement case was objectively baseless. The Federal Circuit remanded the case for further inquiry.

As stated by the Federal Circuit, the issue on remand is limited to the question of whether "Tyco's factual theory of infringement is objectively baseless." This does not mean, as Mutual contends, that the summary judgment decision turns on whether there are factual disputes about what Mutual's experts have to say about the underlying scientific principles. The issue presently before this Court is not whether Mutual's expert opinions are factually correct, but whether or not Tyco had scientific support for its contrary view of the evidence, and whether reliance on that support was reasonable, or objectively baseless.[1] Thus, the summary judgment decision turns on whether there are factual disputes about Tyco's predicate facts supporting its

[1] Mutual argues that the Federal Circuit already credited it with pointing to evidence sufficient to raise a material factual dispute in this inquiry. This is obviously untrue, since the Federal Circuit stated: "We leave it to the district court to determine whether that inquiry can be performed within the context of a summary judgment proceeding or requires a trial." 762 F.3d at 1345. Had the Federal Circuit already determined that a factual dispute had been raised, it would not have left open the possibility that the issue might be resolved at summary judgment.

infringement theory and, if there are none, whether Tyco has shown, as Rule 56 requires, that it is entitled to judgment as a matter of law.

The parties do not dispute the relevant basic legal framework. Under the doctrine known as Noerr-Pennington immunity, a private party is shielded from antitust liability under the Sherman Act when petitioning the government for the enforcement of laws. Eastern R. Presidents Conference v. Noerr Motor Freight, Inc., 365 U.S. 127, 138 (1961). The parties agree that, under the sham exception, Noerr-Pennington immunity does not shield activity which is "a mere sham to cover what is actually nothing more than an attempt to interfere directly with the business relationships of a competitor ." Noerr, 365 U.S. at 144. In Prof'l Real Estate Investors v. Columbia Pictures Indus., 508 U.S. 49, 60-61 (1993) (citations omitted) ("PRE"), the Supreme Court established a two-part test to determine whether the sham exception applies:

> First, the lawsuit must be objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits. If an objective litigant could conclude that the suit is reasonably calculated to elicit a favorable outcome, the suit is immunized under Noerr, and an antitrust claim premised on the sham exception must fail. Only if challenged litigation is objectively meritless may a court examine the litigant's subjective motivation. Under this second part of our definition of sham, the court should focus on whether the baseless lawsuit conceals an attempt to interfere directly with the business relationships of a competitor through the use [of] the governmental process -- as opposed to the outcome of that process -- as an anticompetitive weapon. This two-tiered process requires the plaintiff to disprove the challenged lawsuit's legal viability before the court will entertain evidence of the suit's economic viability.

Plaintiffs contend that Mutual cannot prove that the instant patent infringement litigation is a sham under an objective standard. "Where . . . there is no dispute over the predicate facts of the underlying legal proceeding, a court may decide probable cause as a matter of law." PRE, 508 U.S. at 63.

In PRE, the Supreme Court also held: "Probable cause to institute civil proceedings

requires no more than a 'reasonable belief that there is a chance that [a] claim may be held valid upon adjudication.'" Id. at 62-63 (citations omitted). The party seeking to invoke the sham exception to Noerr-Pennington immunity bears the burden of proof. Id. at 61. Thus, here, Mutual bears the burden of proof that Tyco's factual theory of infringement is objectively baseless.

The parties also do not dispute the following background facts. Mutual submitted to the FDA an ANDA, pursuant to 21 U.S.C. § 355(j), seeking to manufacture and market a 7.5 mg generic temazepam product. Tyco holds U.S. Patent No. 5,211,954 for a 7.5 mg temazepam product. The ANDA specified that the minimum SSA for Mutual's product was 2.2 m^2/g, measured using an assay with outgassing performed at 40°C, whereas the patent specified a maximum SSA of 1.1 m^2/g and did not limit the invention to any particular assay method. Tyco measures the SSA of its temazepam using an assay with outgassing at 105°C. A research study by Mutual's expert demonstrated that, when Tyco's SSA measurement procedure is applied to Mutual's temazepam, the surface area appears to infringe.

In the context of this case, the focus of the objective baselessness inquiry has been defined by the Federal Circuit, which remanded this case with the instruction that this Court must "determine whether Tyco's factual theory of infringement is objectively baseless." 762 F.3d at 1345. The inquiry begins, then, by asking what Tyco's infringement claim is based on.

Tyco relies upon a combination of scientific treatises coupled with the statements of Mutual's expert, Dr. Williams, to demonstrate that its basis for suit was objectively reasonable. First, Tyco points to a passage in the treatise, Industrial Aspects of Pharmaceutics. Göran Alderborn and Christer Nyström, "Characterization of powder surface areas," in Industrial

Aspects of Pharmaceutics (Erik Sandell ed., 1993) ("Pharmaceutics.") This chapter, which is devoted to measurement of the surface area of pharmaceuticals in powdered form, begins by observing that:

> a measurement of the SA of a powder can give a variety of results depending on the method used for the analysis. The SA of a powder must, thus, be defined by the actual method used for the assessment. Consequently, a general definition of the concept of powder SA is not practicable or even possible.

Id. at 8. Later, the treatise states:

> It is usually stated that impurities on the surface of the solid tend to increase the calculated SA. The conditioning of the surfaces is performed by a degassing procedure. General recommendations concerning the conditions during the degassing procedure are difficult to find in the literature. The conditions must be established for each material and kept under strict control in order to obtain reproducible results.

Id. at 12-13. The treatise then discusses two particular degassing techniques, both of which involve the use of temperatures over 100°C. Id. at 13. Tyco contends:

> Because increasing the outgassing temperature facilitates the removal of surface impurities, the following corollary to the principle stated in Pharmaceutics emerges: increasing outgassing temperature (and removing surface impurities) tends to decrease the measured surface area.

(Pls.' Br. 11.)

Second, Tyco cites a reference cited by Mutual's expert, Dr. Williams,[2] the 24th edition of the United States Pharmacopeia ("USP 24"), which states:

> Before the specific surface area of the sample can be determined, it is necessary to remove gases and vapors that may have become physically adsorbed onto the surface after manufacture and during treatment, handling, and storage. If outgassing is not achieved, the specific surface area may be reduced ***or may be***

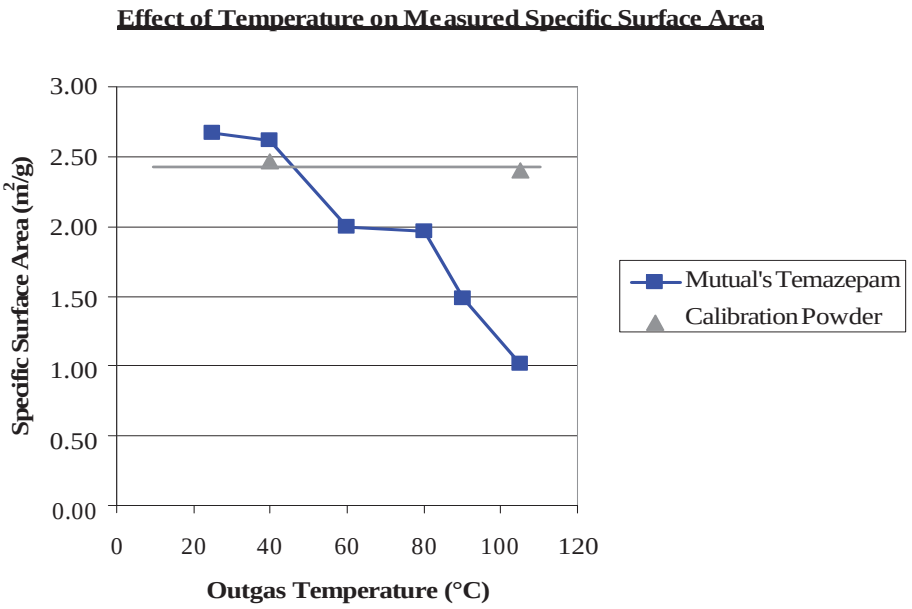
[2] Dr. Williams describes the United States Pharmacopeia as "the authoritative reference for drug and health care products manufactured or sold in the United States." (Williams 11/17/2009 Report ¶ 9.)

> ***variable*** because an intermediate area of the surface is covered with molecules of the previously adsorbed gases or vapors.

United States Pharmacopeia p. 1990 (24th ed., 1999) (emphasis added). Tyco cites this as support for the proposition that higher outgassing temperature may have a variable effect on surface area measurement.

Third, Tyco cites a statement made by Dr. Williams in his expert report: "If there were remaining surface-adsorbed substances then the actual SSA of Mutual's temazepam would generally be higher than the measured values and even further removed from the SSA range of the patent claims." (Williams 11/17/2009 Report ¶ 19.) Tyco points to the use of the word "generally" as implying a concession that, sometimes, the opposite is true. This Court is not persuaded that Tyco has interpreted this statement correctly.

Last, Tyco points to the evidence from actual surface area testing of Mutual's



temazepam. The chart above appears in Dr. Williams' expert report and presents the results of a

study that he did. (Williams 11/17/2009 Report ¶ 24.) Tyco points out that this study, done by Mutual's expert, provides scientific evidence that raising the outgassing temperature leads to lower SSA measurements for Mutual's actual product.

Tyco contends that this material shows that its infringement theory has a basis in scientific fact and cannot therefore be objectively baseless. Now, it is Mutual's burden to demonstrate that the material upon which Tyco relies is insufficient to demonstrate a basis in scientific evidence. It is not enough to show that Mutual's experts, if credited, have demonstrated that Mutual's temazepam did not infringe. Rather, Mutual must demonstrate that no reasonable person could have relied upon Tyco's proffered material to support the belief that he had a reasonable possibility of prevailing on an infringement claim.

Mutual first points to the evidence from its expert, Dr. Gardella, who opined that the 40°C outgassing procedure specified in Mutual's ANDA was appropriate, and there was no scientific basis to assert the contrary. This raises no factual dispute over the specific factual bases for Tyco's infringement theory. Tyco's theory rests on the proposition that raising the outgassing temperature might have resulted in a lower, infringing surface area measurement. Dr. Gardella's opinion about the use of a 40°C outgassing procedure simply disagrees with Tyco. Dr. Gardella did not purport to show why the treatises and specific reasoning underlying Tyco's position make it unreasonable.

Mutual next points to the evidence from its expert, Dr. Williams, who stated that incomplete outgassing would result in a falsely low SSA measurement, and that raising the outgassing temperature to increase the completeness of the outgassing process would result in higher surface area measurements. Again, however, Dr. Williams does not address the specific

facts that form the basis for Tyco's theory of infringement. He does not attempt to demonstrate why Tyco's theory, based upon these scientific treatises, is so untenable as to be a sham.

Last, Mutual cites a similar statement from Dr. Gardella, who stated that Tyco's theory was not scientifically plausible. Again, Dr. Gardella does not here address the specific treatises or reasoning that form the basis for Tyco's theory of infringement.

Mutual's opposition does little to address the four pieces of material that Tyco points to as the factual foundation of its theory of infringement. Crucially, Mutual does not challenge the Pharmaceutics reference, except to argue that Tyco cannot show that the Pharmaceutics reference applies to temazepam. Again, in making this point, Mutual forgets that it bears the burden of proof. Tyco has no obligation to prove that its factual theory is not baseless; again, Mutual bears the burden of showing that Tyco's use of the Pharmaceutics reference was objectively baseless.

Other than this point, Mutual's response to the Pharmaceutics reference is to say that it demonstrates a factual dispute. As discussed, this is only true if one accepts Mutual's position that a factual dispute over the opinions of its own experts suffices to defeat the motion for summary judgment, but Mutual has misunderstood the issues. As to the Pharmaceutics reference, Mutual bears the burden of showing that Tyco's use of that specific reference as a factual foundation for its theory was objectively baseless. Mutual has offered nothing that would persuade a reasonable jury that use of the Pharmaceutics reference as part of the factual foundation for its theory of infringement was objectively baseless.

Also, crucially, Mutual's challenge to the USP reference – which its expert concedes is authoritative – is to argue that it does not say what it plainly says: incomplete outgassing may

produce variability in SSA measurements. Mutual argues that this means only that incomplete outgassing produces only overestimates of SSA – but that interpretation simply writes "or may be variable" out of the sentence. Mutual has offered nothing that would persuade a reasonable jury that use of the USP 24 reference as part of the factual foundation for its theory of infringement was objectively baseless.[3] If incomplete outgassing produces variable results, it appears logical to infer that complete outgassing could produce results that could be higher or lower than the measurements obtained with incomplete outgassing. Mutual has not offered anything to challenge this inference.

Last, as to Dr. Williams' research study on outgassing temperature and SSA measurement, Mutual points to Dr. Williams' theory about his findings: they are explained by heat fusing particles together, rather than by increases in the accuracy of the SSA measurement. Here, again, Mutual has the wrong issue in focus. Were this Court tasked with determining the ultimate scientific truth about outgassing temperature and SSA measurement, Dr. Williams' explanation for the results he obtained might well be important. But that is not the task here. The Court must determine whether Tyco's reference to Dr. Williams' research results as factual support for its theory of infringement is baseless.

In summary, based upon Plaintiff's submissions, there is the following material to support Plaintiff's claims:

1. Pharmaceutics states that a measurement of the surface area of a powder can give a variety of results depending on the method used for the analysis.
2. Pharmaceutics states that the conditions of outgassing must be established

[3] Moreover, even Mutual's expert, Dr. Williams, stated that incomplete outgassing may produce measurements that are "variable." (Williams 11/17/2009 Report ¶ 11.)

for each material.

3. Pharmaceutics states that impurities on the surface of a solid tend to increase the calculated surface area.

4. The United States Pharmacopeia states that incomplete outgassing may cause variable SSA measurements.

5. The United States Pharmacopeia states that, in the outgassing process, "elevated temperatures are sometimes applied to increase the rate at which contaminants leave the surface."

6. Dr. Williams' research study demonstrated that increasing the temperature of outgassing of Mutual's temazepam resulted in a decrease in the measurements of specific surface area.

7. Laboratories often apply heat to speed up the outgassing process.

The Federal Circuit was concerned that it saw only evidence supporting Mutual's theory that more complete outgassing should only produce an increase in measured surface area. Now, based on a fuller evidentiary record, this Court finds that the underlying scientific evidence is not as one-sided as Mutual had suggested to the Federal Circuit. Both sides have theories, and supporting evidence.

Mutual has offered evidence to support its theory about the effect of surface impurities on SSA measurement. Mutual's theory is best stated in its responsive L. Civ. R. 56.1 statement:

> 7. The B.E.T. method involves coating a sample of particles with a special type of measuring gas that binds—or "adsorbs"—to the particles' surfaces. The more gas adsorbs to the sample, the greater its SSA.
>
> 8. Before applying the "adsorbate" gas, the particles are "outgassed" to remove any gases or vapors that are already coating them.
>
> 9. If a particle is not fully outgassed, any impurities that sit on the particle's surface will prevent the measuring gas from adsorbing to that area of the surface.
>
> 10. Because less of the measuring gas will be adsorbed for a sample that has not been fully outgassed, the resulting SSA measurement will necessarily be lower

than the particles' true SSA.

11. Outgassing does not require any heat, but laboratories often apply heat to speed up the process.

Tyco's theory differs fundamentally because it rests on the proposition, taken from the Pharmaceutics reference, that impurities on the surface of the solid tend to increase the calculated surface area.[4] The parties agree that outgassing tends to remove impurities from the surface of the particle, and that heat may speed up the outgassing process. Because heat may speed up the outgassing process, Tyco theorized that increasing the outgassing temperature will facilitate the removal of surface impurities.[5] Although the parties dispute the effect of the higher outgassing temperature on Mutual's temazepam, there does not appear to be any dispute that, in some cases, increasing the outgassing temperature does facilitate the removal of surface impurities. Thus, if the statement in Pharmaceutics is accepted as a predicate, Tyco's theory of infringement follows logically: if impurities on the surface of the solid tend to increase the calculated surface area, and outgassing at higher temperatures facilitates the removal of impurities, then outgassing at higher temperatures would be expected to decrease the measured surface area.

Furthermore, it appears to have been reasonable for Tyco to have been uncertain about how to best measure the surface area of Mutual's temazepam prior to experimenting with it in

[4] This is the crux of the present factual dispute between the parties: they disagree over whether impurities present on the surface of the temazepam during surface area measurement cause an underestimate or an overestimate of surface area.

[5] The United States Pharmacopeia, which the parties agree is authoritative, states that elevated temperatures may increase the rate at which contaminants leave the surface of the material. USP 24 at 1991.

the laboratory. Pharmaceutics states that the conditions of outgassing must be established for each material. Mutual has not presented any evidence that there is one standard and unvarying procedure for the measurement of specific surface area for pharmaceutical powders. Nor has Mutual presented evidence that Tyco's method for measuring the surface area of its temazepam, involving outgassing at 105°C, is necessarily scientifically inappropriate or unsound. This Court concludes that, as an objective matter, Tyco had a reasonable scientific basis for believing that there was a chance that its patent infringement claim would be found valid upon adjudication.

As discussed above, the goal of this inquiry is not to determine which party has the theory with the stronger scientific foundation. Rather, in the objective baselessness inquiry, on summary judgment, the question is whether Mutual has sufficient evidence proving that Tyco's theory has no factual basis whatever to allow the matter to go to a jury. Mutual has not shown that it has sufficient evidence to prove that Tyco's theory has no factual basis whatever. Mutual has shown that its own theory has a scientific foundation, but Mutual has not pointed to evidence which could prove to a reasonable jury that Tyco's theory has none. In particular, Mutual has not pointed to evidence which could prove that reliance on the Pharmaceutics reference was objectively baseless.

This Court determines that Mutual has failed to demonstrate that Tyco's factual theory of infringement is objectively baseless.[6] As to the availability of the sham litigation exception to

[6] The Court notes the following points, which were not relied on in making today's decision. Tyco originally moved for partial summary judgment on the Noerr-Pennington issue on September 21, 2012. In their responsive L. Civ. R. 56.1 statement filed October 22, 2012, Defendants conceded that they needed to get multiple SSA measurements done on multiple batches of temazepam before they got a batch of temazepam that met the specifications of the ANDA. (Defs.' 10/22/2012 56.1 Stmt. ¶¶ 25-35.) On two occasions, the sample tested **lower** than the ANDA SSA specification. (Id. at ¶ 32.)

Noerr-Pennington immunity, Tyco's motion for partial summary judgment will be granted: Tyco's filing of the complaint for patent infringement in this case is protected by Noerr-Pennington immunity. As to that part of the Sixth Counterclaim that alleges anticompetitive conduct through sham litigation, judgment will be entered in favor of Tyco.

As to the issue of the citizen's petition to the FDA, the Federal Circuit vacated this Court's grant of summary judgment to Tyco that the petition was not a sham. 762 F.3d at 1347. After discussing the factual issues with respect to the objective baselessness inquiry, the Federal Circuit stated:

> There remains an open issue, however, as to whether the filing of the citizen petition caused any antitrust injury to Mutual. In this court, neither party has pointed to anything in the record establishing that the citizen petition was the cause of a delay in the approval of the ANDA. In support of its contention that the FDA's approval was delayed "solely because of Tyco's petition," Mutual cites only the ANDA approval letter. The letter, however, does not say anything about a delay due to the citizen petition. On remand, the district court should determine whether Mutual suffered an anticompetitive harm in the form of a delay in the approval of its ANDA due to the filing of Tyco's citizen petition with the FDA. Tyco would be entitled to summary judgment if there is no evidence that the citizen petition caused a delay in the approval of Mutual's ANDA.

Id. at 1348-49. Now, after remand, Tyco moves for partial summary judgment on Mutual's citizen petition counterclaim, on the ground that Mutual has no evidence that the citizen petition caused a delay in the approval of Mutual's ANDA.

Moreover, in Dr. Williams' expert report, he reported on other research he did comparing SSA measurements of Mutual temazepam and Sandoz temazepam at different outgassing temperatures. (Williams 11/17/2009 Report ¶ 32.) Dr. Williams stated: "These results indicate that the two materials react differently to elevated temperatures." (Id.) This suggests, as the Pharmaceutics reference noted, that conditions of outgassing "must be established for each material." Pharmaceutics at 13. In regard to temazepam, knowing what is appropriate for one preparation of temazepam does not enable one to predict the conditions of outgassing appropriate for a different one.

As with the sham litigation issue, the nonmovant bears the burden of proof, and so Tyco satisfies its initial summary judgment by pointing to the absence of evidence to support finding causation. The burden then shifts to Mutual to point to evidence sufficient to persuade a reasonable jury that Tyco's citizen's petition to the FDA caused a delay in FDA approval of Mutual's ANDA.

Mutual points to evidence which largely bases a causal inference on the timing of events, but there is one more direct piece of evidence, the deposition testimony of Robert Dettery: he stated that an FDA official told him "that there was a blocking petition that was preventing our 7.5-milligram ANDA from being approved." (Dettery Dep. 164:3-11.) Tyco has not argued that this testimony is inadmissible, and so, for purposes of summary judgment, it will be credited. Mutual has pointed to sufficient evidence to allow a reasonable jury to find that the citizen's petition delayed approval of Mutual's ANDA. This defeats the motion for partial summary judgment on this issue. As to the citizen's petition to the FDA, the motion for partial summary judgment will be denied.

For these reasons,

IT IS on this 29th day of May, 2015

ORDERED that Plaintiffs' motion for partial summary judgment (Docket Entry No. 534) is **GRANTED** in part and **DENIED** in part; and it is further

ORDERED that, as to the issue of Noerr-Pennington immunity for the citizen's petition to the FDA, the motion is **DENIED**; and it is further

ORDERED that, as to the issue of the availability of the sham litigation exception to Noerr-Pennington immunity, the motion will be **GRANTED**, and Judgment will be entered in

favor of Plaintiffs on that issue.

s/ Stanley R. Chesler
Stanley R. Chesler, U.S.D.J.